



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,329	01/15/2004	Igor E. Bondarev	04-4008-US (501661.20001)	6389
7590 REED SMITH LLP Suite 1400 3110 Fairview Park Drive Falls Church, VA 22042			EXAMINER WOLLENBERGER, LOUIS V	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Office Action Summary</b></p>	<p><b>Application No.</b></p> <p>10/758,329</p>	<p><b>Applicant(s)</b></p> <p>BONDAREV ET AL.</p>	
	<p><b>Examiner</b></p> <p>Louis V. Wollenberger</p>	<p><b>Art Unit</b></p> <p>1635</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-18, 20-27, 29-38 and 41-58 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3, 5, 6, 17, 18, 20, 21, 27, 29-35 and 41-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7-16, 22-26, and 36-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/13/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/13/07 has been entered.

### ***Status of Application/Amendment/Claims***

Applicant's response filed 6/13/07 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 6/13/06 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 6/13/06, claims 1-3, 5-18, 20-27, 29-38, and 41-58 are pending.

Claims 3, 5, 18, 20, 30-35, and 41-58 remain withdrawn.

Claims 2, 6, 17, 21, 27, and 29 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to inventions non-elected, there being no allowable generic or linking claim, as explained below.

Claims 1, 7-16, 22-26, and 36-38 are examined herein.

***Election/Restrictions***

Applicant's amendment to the claims now requires the Examiner to search and examine at least three different methods of treating cancer comprising the administration of AZT, ddI, or d4T. Previously, to fully examine each of the claims it has only been necessary to search and examine methods comprising the use of AZT, as each of the compounds was recited in the alternative. Currently, however, the compounds are recited in separate, dependent claims, requiring a search and examination of methods using each compound.

The inventions are distinct because they have materially different designs and mutually exclusive characteristics. See MPEP § 806.05(j). For instance, the methods as now claimed in claims 2, 17, and 27 require the administration of ddI, which is not specifically required by the methods of claims 6, 21, or 29, which require administering d4T, or the methods of claims 1, 7-16, 22-26, and 36-38, which include a method requiring the administration of AZT. Accordingly, the methods require the administration of structurally and functionally distinct compounds. The different methods do not overlap in scope since the compounds have mutually exclusive characteristics. Furthermore, there is nothing of record to show the different inventions to be obvious variants of one another.

There is an examination and search burden for these patentably distinct methods due to their mutually exclusive characteristics. The different methods would require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to the method of using

one compound would not likely be applicable to another compound; and/or the different inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Should applicant traverse on the ground that the different methods are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the methods to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the methods unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other methods.

To date, Applicant has received an action on the merits for claims drawn to methods of treating cancer, interfering with the lengthening of telomeres and L1RT activity, and inhibiting the growth of a telomerase negative cell, comprising administering to an individual, cell, or system a therapeutically effective amount of AZT. Prior art applied to the claims and grounds of rejection set forth under 35 USC §102 and §103 have all been directed to the AZT embodiment.

While the claims examined thus far have included the alternative methods of administering ddI, d4T, or AZT, the different analogs have been presented as alternatives in a Markush style listing, and it has not been necessary to search and examine each member of the Markush to fully and adequately examine each of the claims as a whole. The claims have been properly rejected over the prior art with regard to the administration of AZT. Thus, Applicant has received an action on the merits with regard to the claimed methods of administering AZT.

As explained above, a search and examination of the claims as presented on 6/13/07 would require the Examiner to search and examine each member of the original Markush group in separate claims, requiring different keyword searches and considerations of the patent and non-patent literature with regard to novelty, obviousness, and enablement, imposing a serious burden on the Examiner.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 2, 6, 17, 21, 27, and 29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

However, Applicant is invited to submit a generic claim linking the different methods. The full scope of the linking claim would be examined on the merits along with the elected embodiment directed to the use of AZT.

Upon submission of a linking claim, the restriction requirement among the linked inventions would be **subject to** the nonallowance of the linking claim(s).

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Art Unit: 1635

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

***Claim Objections—withdrawn***

The objection to Claims 2, 17, 24, 26–28, and 37 because the claims recite limitations to non-elected inventions is withdrawn in view of Applicant's amendments to the claims.

\*\*\*

The objection to Claims 2, 6, 17, and 21 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of Applicant's amendment to the claims.

\*\*\*

The objection to Claim 4 is moot; Applicant has cancelled claim 4.

***Claim Rejections - 35 USC § 112, second paragraph—withdrawn***

The rejection of Claim 28 under 35 U.S.C. 112, second paragraph, as being indefinite is moot; Applicant has cancelled claim 28.

\*\*\*

The rejection of Claim 16 as being indefinite because of insufficient antecedent basis is withdrawn in view of Applicant's amendment to the claim.

\*\*\*

***Claim Rejections - 35 USC § 112, first paragraph—withdrawn***

The rejection of Claims 1, 2, 4, 6, 8, 9, 16, 17, 19, 21, 23, and 25 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicant's amendments to the claims.

\*\*\*

The rejection of Claims 1, 2, 4, 6-15, 39 and 40 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicant's amendments to the claims.

\*\*\*

The rejection of Claims 39 and 40 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is moot; Applicant has cancelled claims 39 and 40.

***Claim Rejections - 35 USC § 103—withdrawn***

The rejection of Claims 1, 2, 4, 6-17, 19, 21-29, and 36-38 under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (1997) *Cancer Res.* 57:2341-5, Delap et al. (1991) *Proc. Annu. Meet. Am. Soc. Clin. Oncol.* 10:A295, Doroshov et al. (1994) *Proc. Annu. Meet. Am. Soc. Clin. Oncol.* 13:146, Gomez et al. (1998) *Biochemical Biophysical Res. Comm.* 246:107-110, Bryan et al. (1997) *Nature Medicine* 3:1271-1274, Bryan et al. (1997) *Eur. J. Cancer* 33:767-



Art Unit: 1635

773, and Kuo et al. (1998) *Biochemical Biophysical Res. Comm.* 253:566-570 is withdrawn in view of the rejections under 35 USC §102, below.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-16, 22-26, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Delap et al. (1991) *Proc. Annu. Meet. Am. Soc. Clin. Oncol.* 10:A295, as evidenced by Bryan et al. (1997) *Nature Medicine* 3:1271-1274, Bryan et al. (1997) *Eur. J. Cancer* 33:767-773, and Kuo et al. (1998) *Biochemical Biophysical Res. Comm.* 253:566-570.

The instant claims are drawn to a method of treating cancer, inhibiting cell growth, and interfering with LIRT activity in an individual, cell, and system, comprising administering AZT.

The preambles of the instant claims give life and meaning to the claimed method only to the extent that they require administering AZT to an individual (or to a cell or system thereof) suffering from a cancer cell or comprising cells characterized by alternative lengthening of telomeres, or ALT.

The “wherein” clauses recited in the claims are given no patentable weight, as they merely recite intended effects achieved by the process step positively recited in the body of the claim: namely, administering AZT to an individual, cell, or system (MPEP 2111.04).

That is, the body of the instant claims fully and intrinsically set forth all of the limitations of the claimed invention (MPEP 2111.02, Section II). The “wherein” clauses add no material or manipulative difference to the recited method. The desired effect recited in the “wherein” clauses would necessarily flow from the method positively recited in the body of the claim.

Absent convincing evidence to the contrary, prior art which teaches each of the material and method step limitations in the instant claims would necessarily produce the effects recited in the claims (MPEP 2112).

Delap et al. taught a method for treating patients suffering from breast, colorectal, ENT, lung, and sarcoma cancer comprising the administration of AZT to said patients. Of the 11 patients treated, 3 noted improvement in their cancer-related symptoms; 2, temporary stabilization of disease; 3, no response; and 3 were too early to evaluate.

The prior art indicates that alternative lengthening of telomeres is present in a variety of different tumors and tumor cell lines, including bladder carcinoma, fibrosarcoma cell lines, and breast carcinoma, as evidenced by Bryan et al. (See Table 1, page 1271). For instance, Bryan et al. report that 29% of breast cancer specimens assayed were telomerase negative (page 1271) and at least one of the specimens displayed long telomeres. Bryan et al. teach that other reports, too, are consistent with the presence of ALT in tumors. For example, Bryan et al. cite a report in which 2 out of 56 renal carcinomas were telomerase negative and had cell clones with greatly

Art Unit: 1635

elongated TRFs (page 1272). Five out of 47 melanomas lacked telomerase activity. Also, a neuroblastoma had elongated TRFs. Thus, in this report, Bryan et al. teach that a measurable percentage of tumors from different tissues have ALT type cells.

In another report, Bryan et al. (1997) *Eur. J. Cancer* 33:767-773 teach that ALT does not correlate with the method of immortalisation of the cell line. There are examples of telomerase-negative cell lines among those immortalised with SV40, HPV, and chemical carcinogens, and in spontaneously immortalised cell lines (page 769). There is also no correlation between telomerase activity and cells of a particular cell type; there are both telomerase negative and positive fibroblast, epithelial, and mesothelial cell lines (page 769, 2<sup>nd</sup> column). Additionally, they teach that cells of the same type and from the same individual may also be either telomerase or ALT-positive (page 769).

Similarly, the instant specification states at page 2 that ALT has been reported in up to 30% of human tumors of different types, tumor-derived cell lines and human cell lines immortalized in vitro, and up to 50% in some subsets of tumors and immortalized cell lines.

Kuo et al. teach that L1 transcripts are present in a large number of solid tumors and tumor cell lines (page 566). Applicants acknowledge this in their remarks submitted 4/10/06 at page 14.

Thus, although, Delap et al. are silent as to the telomere lengthening characteristics and LINE-1 activity of the cancer cells in the patients treated with AZT, there is sufficient evidence in the prior art and on the basis of statements in the instant application to indicate that one or more of the cancers or patients treated by Delap et al. contain cells displaying ALT characteristics. Moreover, it is not necessary for a rejection of the claims under this section for

Art Unit: 1635

Delap et al. to have taught or recognized the ALT-specific properties of AZT, if any, since such properties are inseparable from the compound itself (MPEP 2112, II).

Burden is shifted to the Applicant to show by way of evidence that the cancers and/or patients treated by Delap et al. do not contain cells displaying ALT characteristics or LINE-1 activity, and that the administration of AZT to said patients would not produce the intended effects.

Absent such evidence, Delap et al. is considered to anticipate the instant claims.

MPEP §2112 Requirements of Rejection Based on Inherency; Burden of Proof

A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

**Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.**

A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

\*\*\*

Art Unit: 1635

Claims 1, 7-16, 22-26, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Doroshow et al. (1994) *Proc. Annu. Meet. Am. Soc. Clin. Oncol.* 13:146, as evidenced by Bryan et al. (1997) *Nature Medicine* 3:1271-1274, Bryan et al. (1997) *Eur. J. Cancer* 33:767-773, and Kuo et al. (1998) *Biochemical Biophysical Res. Comm.* 253:566-570.

Doroshow et al. taught a method for treating cancer comprising administering AZT in combination with cisplatin. As many as 25 patients displaying tumor types including lung, breast, ovary, and others were said to be treated with the method. It is said that 7 patients responded with a stable disease profile.

Bryan et al. (1997) *Nature Medicine* 3:1271-1274, Bryan et al. (1997) *Eur. J. Cancer* 33:767-773, and Kuo et al. (1998) *Biochemical Biophysical Res. Comm.* 253:566-570 are relied on for the reasons given above.

Accordingly, Doroshow et al. anticipate the instant claims.

\*\*\*

Claims 1, 7-16, 22-26, and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Au et al. (U.S. Patent 6,995,145), as evidenced by Reddel et al. (2001) *Radiation Res.* 155:194-200, and Kuo et al. (1998) *Biochemical Biophysical Res. Comm.* 253:566-570.

Au et al. disclose and claim a method for treating cancer in humans comprising administering AZT in combination with other therapeutic agents (see cols. 11-13, for example, and claim 27).

Several different cancers are said to be treatable by the method, including, colon, prostate, ovarian, and breast cancer and all those recited at column 12.

A number of different human tumors exhibit ALT and/or comprise cells that are telomerase negative, as evidenced by Reddel et al. These include renal cell carcinomas, osteosarcomas, adrenocortical, ovarian, melanoma, and breast carcinomas (Table 1).

Kuo et al. teach that L1 transcripts are present in a large number of solid tumors and tumor cell lines (page 566). Applicants acknowledge this in their remarks submitted 4/10/06 at page 14.

Thus, although, Au et al. are silent as to the telomere lengthening characteristics and LINE-1 activity of the cancer cells in the patients said to be treatable with AZT, there is sufficient evidence in the prior art and on the basis of statements in the instant application (page 2) to indicate that one or more of the cancers or patients disclosed as being treatable with the AZT combination therapy by Au et al. would contain cells displaying ALT characteristics and/or having LINE-1 activity.

Burden is shifted to the Applicant to show by way of evidence that the cancers and/or patients recommended for treatment with AZT by Au et al. do not and would not contain cells displaying ALT characteristics or LINE-1 activity, and that the administration of AZT to said patients would not produce the intended effects (MPEP 2112).

Absent such evidence, Au et al. is considered to anticipate the instant claims.

\*\*\*

Claims 1, 7-16, 22-26, and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Calabressi et al. (US 6,365,578), as evidenced by Bryan et al. (1997) *Nature Medicine*

3:1271-1274, Reddel et al. (2001) *Radiation Res.* 155:194-200, and Kuo et al. (1998) *Biochemical Biophysical Res. Comm.* 253:566-570.

Calabressi et al. taught and claim a method for treating carcinomas and particularly human colon adenocarcinomas in a patient comprising administering AZT together with a second therapeutic component. Various dosages and methods of delivery are set forth (cols. 1 and 2). In vitro and in vivo embodiments are disclosed and exemplified.

ALT and/or telomerase-negative cells are found in a significant proportion of human tumors and tumor-derived cells lines, including several different carcinomas, as evidenced by Bryan et al. (1997) *Nature Medicine* 3:1271-1274, Reddel et al. (2001) *Radiation Res.* 155:194-200, and the statements made at page 2 of the instant specification. LINE-1 activity or transcripts are found in several tumors, as evidenced by Kuo et al. (1998) *Biochemical Biophysical Res. Comm.* 253:566-570.

Accordingly, Calabressi et al. anticipate the instant claims, since Calabressi et al. taught a method for treating cancer in a mammal, including human colon adenocarcinoma, comprising administering AZT, and there is reason to believe that such a cancer recommended for treatment by Calbressi et al. would necessarily comprise cells having the characteristics recited in the instant claims.

Burden is shifted to the Applicant to show by way of evidence that the human colon adenocarcinomas and other carcinomas recommended for treatment by Calabressi et al. with AZT would not possess the biochemical characteristics recited in the claims.

Art Unit: 1635

***Response to Applicants' Arguments***

Applicants' arguments presented on 6/13/07 not specifically addressed above are considered to be moot in view of Applicants' amendments to the claims and in view of the new and/or reiterated rejections stated herein, above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LW

Art Unit 1635

August 15, 2007

/Sean McGarry/  
Primary Examiner  
AU 1635